REMARKS

Allowable Subject Matter

Applicants gratefully acknowledge the Examiner's indication that claims 51, 54-57, 60-98, and 101-103 recite allowable subject matter. See pages 1 and 4 of the Office Action.

Withdrawal of Finality

In the Office Action of August 24, 2006, claims 25, 26, 33, 35, 38-42, 45-47, and 50-66 were rejected under 35 USC 112, second paragraph. While claim 100 was pending at the time, this claim was not included in the rejection under 35 USC 112, second paragraph.

In response to the Office Action of August 24, 2006, applicants filed a Reply on December 22, 2006. Claim 100 was not amended in this Reply.

In the Final Office Action issued March 14, 2007, claim 100 was rejected under 35 USC 112, second paragraph. This is a new ground of rejection which was clearly not necessitated by any amendment made by applicants.

Thus, it is respectfully submitted that the issuance of a Final Office Action is premature. Withdrawal of the Finality is respectfully requested.

Amendments

In order to facilitate prosecution, the claims are amended such that claim 60 is now the sole independent claim. As noted above, the Examiner has already indicated that claim 60 recites allowable subject manner. Thus, claim 60 is in condition for allowance, and all remaining claims depend from allowable claim 60.

Claims 33, 35, 39, 40, 42, 45-47, 50-59, 61-63, 65, 66, 73 and 99-101 are cancelled. Claim 103 is amended to correct the name of the recited compound. See, e.g., the structural formula for compound 47 in Example 16 and in the Table at page 133. Claims 26 and 60 are amended to correct minor typographical errors. To reduce the number of claims, claim 25 is amended to incorporate the recitation of claim 35, and claim 64 is amended to incorporate the recitation of claim 66. Also, claim 41 is amended to incorporate the recitation of claim 35 and to depend directly from claim 60.

Claims 25, 64, and 67 are amended to be multiply dependent on claims 60, 96, 102,

and 103 (see also new claim 106). New claim 104 is similar to claim 41, except that the at least one additional agent is defined as interferon α or ribavirin. See, e.g., page 2, lines 20-30 which describe the use of interferon α and ribavirin in HCV treatment. Like method claim 26, new composition claim 105 and new compound claim 106 recite that the compound is a pharmaceutically acceptable sodium salt. New claim 107 recites that the HCV is genotype 1b. See, e.g., page 142, lines 13-18.

These amendments clearly reduce the number of issues for appeal. Moreover, these amendments place the application in condition for allowance. Entry of the amendments is respectfully requested.

Rejection under 35 USC §103(a) in view of Kong et al. (US 6,881,741)

At page 2 of the Office Action, the Examiner states that this rejection is being maintained as to claims 25, 26, 33, 35, 38-42, 45-47, 50-53, 58, 59, and 99 (the inclusion of claim 51 is presumed to be an error). This rejection is respectfully traversed.

As discussed in the prior Reply, US 6,881,741, is not prior art, for purposes of 35 USC 103, with respect to the claimed subject matter. The comments in the most recent Office Action regarding this rejection do not address this point.

US 6,881,741 is assigned to ViroChem Pharma Inc. The instant application is also assigned to ViroChem Pharma Inc. by virtue of the assignment recorded at reel 016330/ frame 0677. The instant application and US 6,881,741 were, at the time the invention of the instant application was made, commonly owned by Shire BioChem Inc. Both US 6,881,741 and the instant application were then subsequently assigned to ViroChem Pharma Inc. Thus, US '741 is not prior art under 35 USC 103(c). See MPEP §706.02 (l)(2).

In any event, the rejection is not applied to claim 60. Thus, the rejection is rendered moot by the above amendments whereby claim 60 is made to be the sole independent claim.

In view of the above remarks, withdrawal of the rejection is respectfully requested.

Obviousness-type Double Patenting Rejection in view of Kong et al. (US 6,881,741)

At page 3 of the Office Action, the Examiner states that this rejection is being maintained as to claims 25, 26, 33, 35, 38-42, 45-47, 50-53, 58, 59, and 99 (here again, the inclusion of claim 51 is presumed to be an error). This rejection is respectfully traversed.

It is noted that there is a pending continuation application of US 6,881,741, i.e. Serial No. 11/042,442, filed January 26, 2005.

In any event, the rejection is not applied to claim 60. Thus, the rejection is rendered moot by the above amendments whereby claim 60 is made to be the sole independent claim. Thus, withdrawal of the obviousness-type double patenting rejection is respectfully requested.

Rejection under 35 USC §112, second paragraph

Claim 100 is rejected as allegedly being indefinite with respect to the first compound recited in the claim. This rejection is rendered moot by the cancellation of claim 100. Withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Rejection of Claims 40 and 62 under 35 USC §112, first paragraph

Claims 40 and 62 are rejected under 35 USC §112, first paragraph, on grounds of lack of written description and lack of enablement. .

In the rejection, the Examiner responds to applicants' prior arguments by asserting that the "argument that one skilled in the art is 'aware of classes of agents does not offer any support for the lacking of description." Applicants disagree.

It is be now well settled law that the test for the written description requirement under 35 USC 112, first paragraph, is whether the disclosure reasonably conveys to one of ordinary skill in the art that applicants' had possession of the claimed subject matter as of the filing date of the application. See, e.g., *Chiron Corp. v. Genentech*, 70 USPQ2d 1321, 1327 (Fed. Cir. 2004), *Vas-Cath, Inc. v. Mahurkar,* 19 USPQ2d 1111 (Fed. Cir. 1991), and *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1983). Furthermore, *ipsis verbis*, i.e., express language, is not required to satisfy the requirement. See, e.g., *Fujikawa v. Wattanasin,* 39 USPQ 1895 (Fed. Cir. 1996).

If one of ordinary skill in the art understands the terminology, and that terminology defines a well known and recognizable group of agents, than no further "written description" is needed. That which is well known in the art need not be disclosed in the specification (see, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc*. 802F.2d 1544 (Fed. Cir. 1987)). Claims 40 and 62 recite well known and recognized classes of agents. One or ordinary skill in the art

can readily recognize whether a given agent is or is not a member of a class recited in claims 40 and 62. To convey possession of the concept, it is unnecessary to enumerate each and every member of a class of agents when that class is well known and recognized.

Applicants again assert that the present situation is clearly distinguished from the "reach through" claims discussed in *University of Rochester v. G. D. Searle & Co.*, 69 USPQ 2d 1886 (Fed. Cir. 2004), cited by the Examiner. In *Rochester*, the claims referred to so-called non-steroidal compounds, but the patent did not describe the structure of any compounds of that class. All that the patent disclosed were assays that could be used to identify whether a compound had the desired inhibitory activity. The claims were held to lack written description because the patent failed to describe any compound that had the recited activity, nor was there any evidence that such compounds were known. See *Rochester* at 1895.

Conversely, the classes of agents recited in applicants' claims contain known agents and, thus, the structures of these known agents are known to one of ordinary skill in the art.

Compare, for example, the situation in *Capon v. Eshhar*, 76 USPQ2d 1078 (Fed. Cir. 2005). In *Capon*, the subject matter of the Interference involved chimeric genes containing certain gene segments that were functionally described in the claims (i.e., described in terms of their encoding functions). The Board held the claims of both parties to be unpatentable for lack of written description because their specifications did not describe the chimeric DNA "by reference to knowledge in the art of the 'structure, formula, chemical name, or physical properties.'"

The Court reversed, noting that the structures of the gene segments that made up the chimeric genes were known in the art.

> The "written description" requirement states that the patentee must describe the invention; it does not state that that every invention must be described in the same way. ... Both Eshhar and Capon explain that this invention does not concern the discovery of gene function or structure, as in *Lilly*. The chimeric genes here at issue are prepared from known DNA sequences of known function. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure of formula or chemical name for the nucleotide sequences of the claimed chimeric genes. (*Capon* at page 1085)

Similarly, in the instant case, applicants are not claiming the discovery of new antioxidant agents or antibacterial agents. The relevant claims involve the combined use of known agents

with novel compounds of applicants claimed genus (for which there is more than adequate written description). Compare also *Falkner v. Inglis*, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) where the Court upheld claims that were being challenged for lack of written description requirement. The claims were directed to a vaccine containing a mutant poxvirus having an inactivating mutation in a viral gene, wherein that gene was functionally described as being essential for production of infectious viral particles. The Court noted that there was no length requirement for the adequate written description and that essential genes for poxvirus were known in the art. See *Falkner* at page 1007.

The Examiner further alleges in the rejection that "broad classes of agents have drastically different properties." Although it is unclear what is meant by drastically different, in any event, an assertion that the members of a class have varying properties does not suggest that the class of known agents is not described adequately under 35 USC §112, first paragraph.

Finally, with respect to written description, the Examiner argues that, without description as to specific anti-bacterial agents, "the specification offered insufficient description as to support the scope of the claims." Here, the Examiner's concern seems to breadth of a class of agents. However, it is unclear how a broad class results in a failure to reasonably convey. If an applicant refers to the use a class of agents that is known and well recognized, possession of the concept of the use of that class of agents is reasonably conveyed whether the class contains a few or many members. The comments in the rejection do not suggest otherwise.

In any event, this rejection is rendered moot by the cancellation of claims 40 and 62.

In view of the above remarks, it is respectfully submitted that the applicants' specification reasonably conveys to one of ordinary skill that, at the time of filing, that applicants had possession of the concept of the subject matter recited in claims 40 and 62.

Withdrawal of the rejection under 35 USC §112, first paragraph, for lack of written description is respectfully requested.

Rejection of Claims 40, 41, and 61-63 under 35 USC §112, first paragraph

Claims 40, 41 61, 62, and 63 are rejected under 35 USC §112, first paragraph, as allegedly being non-enabled. This rejection is respectfully traversed.

Firstly, it is noted that claims 40 and 61-63 have been cancelled. Secondly, applicants note that the rejection sets for no rationale as to why claim 61 was rejected. In the prior Office Action issued August 24, 2006, claims 40, 41, 61, 62, and 63 were all rejected under 35 USC 112, first paragraph, on grounds of lack of enablement. With respect to claim 61, the only basis for the rejection was the recitation of "preventing." This term has since been deleted from claim 61. Thus, applicants do not know the reason why the rejection was maintained as to claim 61.

In the rejection, it is asserted that "applicants have presented no factual evidence that how [sic] can the undue experimentation well recognized in the art to be obviated in the absence of dosage, sequence, site ...." However, applicants respectfully submit that the rejection has failed to present factual evidence that undue experimentation is well recognized in the art as to this situation.

Applicants' disclosure clearly provides more than sufficient guidance regarding the dosage and administration of the claimed novel compounds. See, e.g., pages 40-45. As for the additional agents recited in claim 41, i.e., interferon α, ribavirin, silybum marianum, interleukine-12, amantadine, ribozyme, thymosin, N-acetyl cysteine and cyclosporine, as discussed above, these are all well known therapeutic agents. Thus, one of ordinary skill in the art would not only recognize these therapeutic agents, but what also know how such agents are administered and the effective doses employed for such agents. Armed with this knowledge, one of ordinary skill in the art would require **no more than routine experimentation** to make and use the inventive methods recited in claim 41.

Compare, for example, *Merck v. Biocraft*, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989). In that case, the court noted that the procedures used by Merck to determine dose were routine and were the procedures followed by all pharmaceutical companies to determine appropriate dose. See, also, *U.S. v. Telectronics*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), where the court held that one of ordinary skill in the art would know how to conduct a dose response study.

In view of the above remarks, withdrawal of the rejection under 35 USC §112, first paragraph, for lack of enablement is again respectfully requested.

No fee, other than the 3-Month Extension of Time, Notice of Appeal and Extra/Multiple Dependent Claims fees being paid herewith, is believed to be due with this Reply. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Brion P. Heaney/
Brion P. Heaney
Registration No. 32,542
Attorney for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703)243-6333
Facsimile: (703) 243-6410
Attorney Docket No.: VIRO-5

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BPH/cak